

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Harry R. Davis, et al.

Examiner: Shengjun Wang

Serial No.: 10/057,646

Group Art Unit: 1617

Filed: January 25, 2002

Atty. Docket No.: CV01379K

For: Combinations of Bile Acid
Sequestrant(s) and Sterol
Absorption Inhibitor(s) and
Treatments for Vascular Indications

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to Rule 56, it is requested that the documents listed on the accompanying PTO-1449 Form be considered and made of record in the above-identified patent application. Copy(ies) of these references ☒ are attached ☐ were filed in related application U.S. Serial No(s) _____ filed _____, respectively.

(b) No fee is believed due because:

- ☐ This Information Disclosure Statement is being filed within three (3) months of the filing date of the application.
- ☐ This Information Disclosure Statement is being concurrently filed with the above-identified application.
- ☐ This Information Disclosure Statement is being concurrently filed with a Request for Continued Examination (RCE).
- ☐ This Information Disclosure Statement is being filed prior to the mailing of a first Office Action on the merits.

(c) ☒ This Information Disclosure Statement is being filed before the mailing date of any final action, notice of allowance or an action that otherwise closes prosecution; and

☐ Each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or


☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; or

- ☒ The Commissioner is hereby authorized to charge the requisite fee listed on the attached Fee Transmittal Sheet.
- (d) ☐ This Information Disclosure Statement is being filed on or before the payment of the issue fee; and
- ☐ Each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; and
- ☐ The Commissioner is hereby authorized to charge the requisite fee listed on the attached Fee Transmittal Sheet.
- ☒ The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. **19-0365**, Patent Case No. **CV01379K**. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,
SCHERING-PLOUGH CORPORATION

Dated: **February 12, 2004**
SCHERING-PLOUGH CORPORATION
Patent Department, K-6-1, 1990
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530
Facsimile No.: (908) 298-5388

By: _____


Name: **Ann M. Cannoni**
Reg. No.: **35,972**
Attorney of Record
Telephone No.: (908) 298-5024

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VIRGINIA 22313-1450 ON February 12, 2004.
(DATE OF DEPOSIT)

ANN MARIE CANNONI, REG. NO. 35,972
(REGISTERED REPRESENTATIVE)


(SIGNATURE AND DATE)



| | | | | | | | |
|---|---|-------------------------------|---------------------------|-------------------------------------|--|----------------------------------|----------------|
| FORM PTO-1240 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use several sheets if necessary)</i> | <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%;">ATTY. DOCKET NO.: CV01379K</td> <td style="width:50%;">SERIAL NO.: 10/057,646</td> </tr> <tr> <td colspan="2">APPLICANT: Harry R. Davis et al.</td> </tr> <tr> <td>FILING DATE: January 25, 2002</td> <td>GROUP: 1614</td> </tr> </table> | ATTY. DOCKET NO.: CV01379K | SERIAL NO.: 10/057,646 | APPLICANT: Harry R. Davis et al. | | FILING DATE: January 25, 2002 | GROUP: 1614 |
| ATTY. DOCKET NO.: CV01379K | SERIAL NO.: 10/057,646 | | | | | | |
| APPLICANT: Harry R. Davis et al. | | | | | | | |
| FILING DATE: January 25, 2002 | GROUP: 1614 | | | | | | |

U.S. PATENT DOCUMENTS

| *EXAMINER INITIAL | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB- CLASS | FILING DATE IF APPROPRIATE |
|----------------------|--------------------|------------|----------|-----------------------------|---------------|----------------------------------|
| | AB | 10/057,534 | 01/25/02 | Harry R. Davis et al. | | |
| | AC | 10/057,629 | 01/25/02 | Harry R. Davis | | |
| | AD | 10/154,106 | 05/22/02 | Harry R. Davis et al. | | |
| | AE | 10/057,323 | 01/25/02 | Harry R. Davis et al. | | |
| | AF | 10/136,968 | 05/01/02 | Wing-Kee Philip Cho et al. | | |
| | AG | 10/057,339 | 01/25/02 | Teddy Kosoglou et al. | | |
| | AH | 10/247,032 | 09/19/02 | Harry R. Davis | | |
| | AI | 10/056,680 | 01/25/02 | Teddy Kosoglou et al. | | |
| | AK | 10/247,099 | 09/19/02 | Harry R. Davis et al. | | |
| | AL | 10/247,085 | 09/19/02 | John T. Strony | | |
| | AM | 10/247,095 | 09/19/02 | Harry R. Davis | | |
| | AN | 10/246,996 | 09/19/02 | Alexandre P. Lebeaut et al. | | |
| | AO | 10/247,397 | 09/19/02 | Harry R. Davis et al. | | |
| | AP | 10/166,942 | 06/11/02 | Anima Ghosal et al. | | |

FOREIGN PATENT DOCUMENTS

| DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB- CLASS | TRANSLATION | |
|--------------------|------|---------|-------|---------------|-------------|----|
| | | | | | YES | NO |
| AQ | | | | | | |
| AR | | | | | | |
| AS | | | | | | |
| AT | | | | | | |
| AU | | | | | | |
| AV | | | | | | |
| AW | | | | | | |

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

| | |
|----|--|
| AX | ZETIA™ (ezetimibe) Tablets Package Insert (Merck/Schering-Plough Pharmaceuticals) (October 2002) |
| AY | Schering-Plough Reports Financial Results for 2003 Fourth Quarter, Full Year, Monday, January 26, 6:33 am ET |
| AZ | |
| BA | |
| BB | |
| BC | |

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|----------|-----------------|
| EXAMINER | DATE CONSIDERED |
|----------|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Sheet 1 of 1

| | | | |
|---|--|-------------------------------------|---------------------------|
| FORM PTO-449 INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | ATTY. DOCKET NO.: CV01379K | SERIAL NO.: 10/057,646 |
| | | APPLICANT: Harry R. Davis et al. | |
| | | FILING DATE: January 25, 2002 | GROUP: 1614 |

U.S. PATENT DOCUMENTS

| *EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB- CLASS | FILING DATE IF APPROPRIATE |
|----------------------|----|--------------------|----------|-----------------------------|-------|---------------|----------------------------------|
| | AB | 10/057,534 | 01/25/02 | Harry R. Davis et al. | | | |
| | AC | 10/057,629 | 01/25/02 | Harry R. Davis | | | |
| | AD | 10/154,106 | 05/22/02 | Harry R. Davis et al. | | | |
| | AE | 10/057,323 | 01/25/02 | Harry R. Davis et al. | | | |
| | AF | 10/136,968 | 05/01/02 | Wing-Kee Philip Cho et al. | | | |
| | AG | 10/057,339 | 01/25/02 | Teddy Kosoglou et al. | | | |
| | AH | 10/247,032 | 09/19/02 | Harry R. Davis | | | |
| | AI | 10/056,680 | 01/25/02 | Teddy Kosoglou et al. | | | |
| | AK | 10/247,099 | 09/19/02 | Harry R. Davis et al. | | | |
| | AL | 10/247,085 | 09/19/02 | John T. Strony | | | |
| | AM | 10/247,095 | 09/19/02 | Harry R. Davis | | | |
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| | AO | 10/247,397 | 09/19/02 | Harry R. Davis et al. | | | |
| | AP | 10/166,942 | 06/11/02 | Anima Ghosal et al. | | | |

FOREIGN PATENT DOCUMENTS

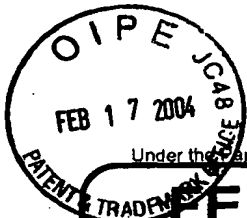
| | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB- CLASS | TRANSLATION | |
|--|----|--------------------|------|---------|-------|---------------|-------------|----|
| | | | | | | | YES | NO |
| | AQ | | | | | | | |
| | AR | | | | | | | |
| | AS | | | | | | | |
| | AT | | | | | | | |
| | AU | | | | | | | |
| | AV | | | | | | | |
| | AW | | | | | | | |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| | | |
|--|----|--|
| | AX | ZETIA™ (ezetimibe) Tablets Package Insert (Merck/Schering-Plough Pharmaceuticals) (October 2002) |
| | AY | Schering-Plough Reports Financial Results for 2003 Fourth Quarter, Full Year, Monday, January 26, 6:33 am ET |
| | AZ | |
| | BA | |
| | BB | |
| | BC | |

| | |
|----------|-----------------|
| EXAMINER | DATE CONSIDERED |
|----------|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



PTO/SB/17 (10-03)

Approved for use through 07/31/2006. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ 180.00

C mplet if Known

| | |
|----------------------|-----------------------|
| Application Number | 10/057,646 |
| Filing Date | 01/25/2002 |
| First Named Inventor | Harry R. Davis et al. |
| Examiner Name | Shengjun Wang |
| Art Unit | 1617 |
| Attorney Docket No. | CV01379K |

METHOD OF PAYMENT (check all that apply)☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None☒ Deposit Account:Deposit
Account
Number
Deposit
Account
Name

19-0365

Schering-Plough Corporation

The Director is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments☒ Charge any additional fee(s) or any underpayment of fee(s)☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.**FEE CALCULATION****1. BASIC FILING FEE**

| Large Entity Fee Code (\$) | Small Entity Fee Code (\$) | Fee Description | Fee Paid |
|-------------------------------|-------------------------------|------------------------|----------|
| 1001 770 | 2001 385 | Utility filing fee | |
| 1002 340 | 2002 170 | Design filing fee | |
| 1003 530 | 2003 265 | Plant filing fee | |
| 1004 770 | 2004 385 | Reissue filing fee | |
| 1005 160 | 2005 80 | Provisional filing fee | |

SUBTOTAL (1) (\$ 0.00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

| Total Claims | Extra Claims | Fee from below | Fee Paid |
|--------------------|--------------|----------------|----------|
| Independent Claims | -20** = | X | |
| Multiple Dependent | -3** = | X | |

| Large Entity Fee Code (\$) | Small Entity Fee Code (\$) | Fee Description |
|-------------------------------|-------------------------------|--|
| 1202 18 | 2202 9 | Claims in excess of 20 |
| 1201 86 | 2201 43 | Independent claims in excess of 3 |
| 1203 290 | 2203 145 | Multiple dependent claim, if not paid |
| 1204 86 | 2204 43 | ** Reissue independent claims over original patent |
| 1205 18 | 2205 9 | ** Reissue claims in excess of 20 and over original patent |

SUBTOTAL (2) (\$ 0.00

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)**3. ADDITIONAL FEES**

Large Entity Small Entity

| Fee Code (\$) | Fee Code (\$) | Fee Description | Fee Paid |
|---------------|---------------|--|----------|
| 1051 130 | 2051 65 | Surcharge - late filing fee or oath | |
| 1052 50 | 2052 25 | Surcharge - late provisional filing fee or cover sheet | |
| 1053 130 | 1053 130 | Non-English specification | |
| 1812 2,520 | 1812 2,520 | For filing a request for ex parte reexamination | |
| 1804 920* | 1804 920* | Requesting publication of SIR prior to Examiner action | |
| 1805 1,840* | 1805 1,840* | Requesting publication of SIR after Examiner action | |
| 1251 110 | 2251 55 | Extension for reply within first month | |
| 1252 420 | 2252 210 | Extension for reply within second month | |
| 1253 950 | 2253 475 | Extension for reply within third month | |
| 1254 1,480 | 2254 740 | Extension for reply within fourth month | |
| 1255 2,010 | 2255 1,005 | Extension for reply within fifth month | |
| 1401 330 | 2401 165 | Notice of Appeal | |
| 1402 330 | 2402 165 | Filing a brief in support of an appeal | |
| 1403 290 | 2403 145 | Request for oral hearing | |
| 1451 1,510 | 1451 1,510 | Petition to institute a public use proceeding | |
| 1452 110 | 2452 55 | Petition to revive - unavoidable | |
| 1453 1,330 | 2453 665 | Petition to revive - unintentional | |
| 1501 1,330 | 2501 665 | Utility issue fee (or reissue) | |
| 1502 480 | 2502 240 | Design issue fee | |
| 1503 640 | 2503 320 | Plant issue fee | |
| 1460 130 | 1460 130 | Petitions to the Commissioner | |
| 1807 50 | 1807 50 | Processing fee under 37 CFR 1.17(q) | |
| 1806 180 | 1806 180 | Submission of Information Disclosure Stmt | 180.00 |
| 8021 40 | 8021 40 | Recording each patent assignment per property (times number of properties) | |
| 1809 770 | 2809 385 | Filing a submission after final rejection (37 CFR 1.129(a)) | |
| 1810 770 | 2810 385 | For each additional invention to be examined (37 CFR 1.129(b)) | |
| 1801 770 | 2801 385 | Request for Continued Examination (RCE) | |
| 1802 900 | 1802 900 | Request for expedited examination of a design application | |

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$ 180.00

SUBMITTED BY

(Complete (if applicable))

| | | | | | |
|-------------------|-------------------|-----------------------------------|--------|-----------|--------------|
| Name (Print/Type) | Ann Marie Cannoni | Registration No. (Attorney/Agent) | 35,972 | Telephone | 908-298-5024 |
| Signature | | | | Date | 02/12/2004 |

WARNING: Information on this form may become public. Credit card information should not be included in this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.